GETTING TO QUALITY

By Iain.D.Miller, Ph.D.

I think we can agree that one of the critical success factors of personalized healthcare is access to high quality testing. But, what is high quality testing? There are lots of definitions of quality but they tend to converge around the perception of the extent to which the product/service meets customer needs in a dependable fashion. In this case, we might define customer needs, amongst other things, with reliable selection of the "right" patients for therapy.

Does the healthcare market deliver high quality testing today? I'd argue that we are not there yet. We are all aware of several studies citing inter-laboratory discordance of up to 20% for well-established immunohistochemistry tests such as ER/PR and Her2. Low-volume labs fare particularly badly in some studies. There are also many sources of potential variability for molecular testing.

One key quality driver is the adoption of products ("kits") developed by leading IVD companies. The core business of these companies is the development of standardized products under stringent QSRs, so they should be part of the solution. Yet, over half of testing is based on local lab-developed tests (LDTs), some of which fall short of accepted definitions of quality. Why do labs use tests developed in house? While this choice is sometimes the result of the lack of availability of kit products, it can be driven by lack of incentives to adopt better-validated (higher quality) products. This is a problem for the nascent personalized healthcare field, as it adversely impacts willingness of diagnostics product companies to invest in evidence, while also potentially impacting the post-market therapeutic profile and utility of targeted medicines. In essence, uncertain quality puts a brake on the necessary industrialization of personalized healthcare, a term I use to mean bringing standardized care to all.

Will we see the broader adoption of high quality tests, such as those developed as companion diagnostics by leading IVD companies in collaboration with pharmaceutical companies? Regulatory draft guidance from the FDA and EC seem to offer little incentive for productization versus local service (LDT). Meanwhile, national initiatives in France (Inca) and the UK (Technology Strategy Board) tend to reinforce established testing paradigms, which are primarily LDT-based, while admittedly adding a layer of quality assurance via external assessment bodies. The good news is that such External Quality Assessment programs, including those being implemented by bodies such as NEQAS

in the UK and the European Society of Pathology, may lead to higher adoption of industrialized (IVD) products and a general rise in concordance across testing sites.

It remains to be seen how the dual challenges of standardization (quality assurance) and product incentivization will be resolved over time, especially for the high complexity/ high Positive Predictive Value tests so badly needed by global healthcare systems.

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